EC-2000-007 IV-D-055

United States Environmental Protection Agency
Enforcement and Compliance Docket and Information Center
Mail Code 2201A
Attention: Docket Number EC-2000-007
1200 Pennsylvania Avenue NW,
Washington, D.C. 20460

Received

FEB 26 2002

Enforcement & Compliance Docket & Information Center

February 27, 2002

Dear Docket Clerk,

PerkinElmer is a global analytical instrument manufacturer with over \$700 million in revenues for the instrument division. As a premiere instrument manufacturer we have always appreciated the needs of the environmental market for accurate, precise, and productive modern instrumentation. We have supported the market in the development of gas chromatography/mass spectrometry, inductively coupled plasma mass spectrometry, and many other instruments, in addition to providing applications, training, and service support.

PerkinElmer supports the EPA efforts to make reporting easier and more modern. We support efforts to be flexible, so that newer technology and a variety of implementations can be supported in a less prescriptive way. It is very important to be consistent with existing regulations from other regulatory groups, both for the market place, which may work with more than one agency and for the manufacturing community, which may supply instruments to laboratories working with more than one agency. We also support efforts to make implementation uniform across the EPA offices and programs, to provide maximum clarity and efficiency.

We do, however, have some concerns about the consistency of the proposed rule when compared to 21 CFR, part 11. PerkinElmer has assigned a committee to develop an implementation plan for 21 CFR and they have taken great strides in planning and implementing projects for compliance in several areas. If this rule requires significantly different technical approaches to electronic signatures or audit trails, we likely will be unable to implement them in the near future. If we did implement a second technical approach at some point, supporting more than one implementation would be confusing to our customers and costly to us. As a publicly held company, we would have to carefully consider the return on our investment for the shareholders.

We are also concerned that the rule extends the scope of 21CFR by including the mechanism for transmission of data. We have not thoroughly investigated this aspect of the rule, but it appears that the choices are limited and may exclude full participation by the marketplace. It might make more sense to consider the mechanism for electronic data delivery in a separate rule and keep this rule as close to 21CFR as possible.

We are concerned about the implementation of the rule from a financial perspective, both for ourselves and for a community battered by decreased investment over the last decade. We want to participate fully in this market and concerns about exclusionary choices and costly repetitive implementations remain. If we are to best serve our customers, advance planning, requirement clarity, and consistency with other agencies mentioned in this rule are key.

Respectfully submitted,

Zoe Grosser and Elaine Le Moine

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